DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
d19446

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/769-3010

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

our ref: 2953689

July 21, 1998

Joseph T. Arana
President
Electronic Support Services, Inc.
6220 Stevenson Way
Las Vegas, NV 89120

Dear Mr. Arana:

An inspection was conducted on May 28, 1998 of your company, Electronic Support Services (ESS), 6220 Stevenson Way, Las Vegas, NV 89120, by Investigator Douglas W.Gronski. He determined that the facility manufactures an electrical muscle stimulator named the ProElecDT2 for Matrix Biokinetics of North Las Vegas, NV. This product is a device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act.

The inspection revealed that this device is adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packaging, storage, or installation are not in conformance with either the Good Manufacturing Practice Regulation (GMPs) or the Quality Systems Requirements (QSRs) for medical devices as set forth in Title 21, Code of Federal Regulations (CFR) Part 820 as follows:

1. ESS does not maintain a Device History Record for the ProElecDT2 devices manufactured. [21 CFR 820.184]

2. Results of finished product testing and criteria for product acceptance are not recorded. [21 CFR 820.80]

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA483 issued to you at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may

take this information into account when considering the award of contracts. Additionally, requests for Certificates of Exportability and to Foreign Governments will not be cleared until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed withing 15 working days, state the reason for the delay and the date on which the corrections will be completed.

Your response should be sent to the following:

Andrea P. Scott
Compliance Officer
U. S. Food and Drug Administration
96 North Third St.
San Jose, CA 95112

Sincerely yours,

Charles D. Maas
Acting District Director

for Patricia C. Ziobro
Director
San Francisco District